

### REMARKS

In reply to the Office Action mailed October 19, 2007, Applicants have amended claims 2 and 3 and cancelled claims 6-11, 13 and 20. Claims 2, 3, 5, 12, 14 to 19, 21, 22, and 42 are pending and under examination.

#### Rejection under 35 U.S.C. 112

Claim 3 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants have amended claim 3 to recite that the composition consists of carrageenan and optionally one or more additional biopolymers. Applicants submit that claim 3, as currently amended, is clear to mean that carrageenan is required in the composition and that the composition can also include another biopolymer that is not required to be carrageenan. Applicants submit that amended claim 3 satisfies the requirements of 35 U.S.C. 112, second paragraph, and request that the corresponding rejection be withdrawn.

#### Rejection under 35 U.S.C. 103(a)

Claims 2, 3, 5, 12, and 14 to 22 were rejected under 35 U.S.C. 103(a) as allegedly obvious over U.S. Patent 6,458,287 (Scott) in view of Watts (WO 98/30207) and further in view of the teachings of Noble (US 4,574,152), Voser (US 3,725,400) and Chromecek (3,886,125). The Examiner asserts that the term "biopolymer" had not been defined in the application and that the term, as understood in the art, refers to any "macromolecule which can be found within a living thing." (See Office Action, page 4.) Applicants have amended claim 3 to recite a specific biopolymer, carrageenan.

Scott discloses microspheres for sustained release of therapeutic agents, which require a macromolecule and at least one water soluble polymer (see Scott at col. 3, lines 27 to 30 and col. 10, lines 43 to 46). According to Scott, a macromolecule is "any molecule having a tertiary and quaternary structure or capable of having a tertiary and quaternary structure." (col. 12, lines 22 to 24). Preferred macromolecules include, e.g., proteins, peptides, carbohydrates, polysaccharides and nucleic acids (col. 12, lines 24 to 30). Nothing in Scott would lead one skilled in the art to use cephalosporin and carrageenan as the macromolecule or in a composition as recited in the claims.

Turning now to the secondary references, applicants submit that none of them, i.e., Watts, Noble, Voser or Chromecek, remedy the deficiencies of Scott. Watts describes, *inter alia*, drug compositions comprising chitosan, type A cationic gelatin, and a therapeutic agent. Noble describes ternary complexes that include cephalosporin complexed with copper (II) ions and an organic nitrogen base. Voser describes isolating cephalosporin C from solutions. Chromecek describes polymer complexes that include a polymer containing aluminum zinc or zirconium metal bound in complex form. Not one of these references provides the motivation or reasoning to include carrageenan and cephalosporin in the microspheres described in Scott. Accordingly, applicants submit that no *prima facie* case of obviousness has been established and that the present rejection should be reconsidered and withdrawn.

Claims 2, 3, 5, 12, 14 to 22, and 42 were rejected as allegedly obvious over Scott in view of Watts and U.S. Patent No. 5,783,561 (Horwitz) and further in view of the teachings of Noble, Voser and Chromecek. Applicants traverse this rejection.

The deficiencies of Scott, Watts, Noble, Voser and Chromecek were discussed above in detail. Horwitz does not remedy the deficiencies of these references. Horwitz describes, *inter alia*, treating gram positive bacterial infections using bactericidal/permeability-increasing (BPI) protein products. Horwitz would not have provided skilled practitioners with any motivation or reason to modify Scott in the way the Office proposes, and apparently Horwitz is not relied upon by the Office for such a teaching. Thus, the combination of Scott, Watts, Horwitz, Noble, Voser and Chromecek do not support a *prima facie* case of obviousness and the rejection should be withdrawn.

Claims 2, 3, 5, 12, 14 to 22, and 42 were rejected as allegedly obvious over Levy et al. (WO96/20698) in view of Scott, Noble, Voser and Chromecek. Applicants traverse this rejection. As noted above, amended claim 3 recites a composition that consists of carrageenan and optionally one or more additional biopolymers. Levy describes biodegradable controlled release nanoparticles as sustained release bioactive agent delivery vehicles. In some embodiments, the nanoparticles include surface modifying agents. Levy recites that polylactic polyglycolic acid copolymer and polycaprolactone are preferred polymers. (See Levy, page 8.) Applicants submit that nothing in Levy would lead one skilled in the art to modify Levy to arrive at Applicants claimed invention, which includes a composition consisting of carrageenan and

optionally one or more additional biopolymers. Moreover, none of Scott, Noble, Voser or Chromecek, for at least the reasons discussed above, cures the deficiencies of Levy. Accordingly, applicants submit that no *prima facie* case of obviousness has been established and that the present rejection should be reconsidered and withdrawn.

#### CONCLUSION

Applicants ask that the proposed amendments be entered and that all rejections and objections be reconsidered and withdrawn. Please apply any other charges or credits to Deposit Account No. 50/2762, referencing Attorney Docket No. C2080-700130.

Respectfully submitted,

/Laurie Butler Lawrence/  
Laurie Butler Lawrence  
Reg. No. 46,593  
Lowrie, Lando & Anastasi, LLP  
Riverfront Office Park  
One Main Street- 11th Floor  
Cambridge, MA 02142

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